

REMARKS

In response to the Notice mailed January 26, 2005, Applicant has accurately represented the changes in the claims that were previously under consideration as set forth in the previously submitted preliminary amendment and the amendments to the claims as currently proposed by the Applicant in response to the Office Action dated June 15, 2004. Claims 1-4, 6-8, 10, 11, 13, 14, and 17-20 are currently pending in the present application. Claims 21 and 39 have been canceled without prejudice in order to expedite the allowance of the present application.

Applicants express their gratitude for courtesies extended by the Examiner during a personal interview with Applicants' representatives Andrew M. Parial and Kenneth I. Kohn conducted October 4, 2004. During the personal interview, all outstanding rejections were discussed. Applicants' representative provided alternative claim language and possible amendments to the claims in order to overcome the outstanding rejections.

Specifically referring to the Office Action, the specification has been objected to for failing to provide proper antecedent basis for the claimed subject matter set forth in claims 21 and 39. Since these claims have been canceled without prejudice from the present application, the objection to the specification has been rendered moot.

Claims 1-4, 6-8, 10, 11, 13, 14, 17-21, and 39 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. In response thereto, the presently pending claims have been amended by deleting the phrase "Lawsonia spp. OmpH" from the pending claims. This amendment is pursuant to suggestions provided by the Examiner during the personal interview. As a result, the presently pending claims are no longer indefinite and reconsideration of the rejection is respectfully requested.

Claims 6-8, 10, 11, 17, 18, 21, and 39 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. More specifically, the Examiner holds that the claims are unclear as to whether the polypeptides comprised at least 70% of the sequence of the full-length of SEQ ID No: 1 or if the claims require only the polypeptide share at least 70% identity with the residues in the sequence of SEQ ID No: 1. Secondly, the Examiner holds that it is unclear what the distinction is among the terms "peptide, oligopeptide, and polypeptide." In response thereto, Applicants point out that the claim language is directed towards polypeptide sharing at least 70% sequence identity with the residues in the sequence of SEQ ID No: 1. Additionally, the claims have been amended by deleting the terms "peptide" and "oligopeptide." Reconsideration of the rejection is respectfully requested.

Claims 19 and 20 have been rejected under 35 U.S.C. §112, second paragraph, for being indefinite. Specifically, the Office Action holds these claims read on the vaccine composition according to claim 16 of the present application; however, claim 18 was canceled from the application in a previously filed amendment. In response thereto, claim 19 has been amended to properly depend upon claim 17, which is currently pending in the present application. Reconsideration of the rejection is respectfully requested.

Claims 1-4, 6-8, 10, 11, 17, 18, 21, and 39 have been rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. According to the Examiner, although the specification provides enablement for an immunogenic polypeptide of SEQ ID No: 1, the specification does not reasonably enablement for any variant or homolog thereof. In response thereto, the presently pending claims have been amended to delete the terms "homolog," "analog," and "derivative" that refer to the polypeptide of SEQ ID No: 1. As a result of the amendments to the claims, the presently pending claims are fully enabled in view of the specification and are directed towards the immunogenic

polypeptides of SEQ ID No: 1. Reconsideration of the rejection is respectfully requested.

Claims 1-4, 6-8, 10, 11, 17, 18, 21, and 39 have been rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. According to the Office Action, Applicants have not provided any examples of homologs or variants of the protein that mimic or cross-react with antibodies to SEQ ID No: 1; therefore, Applicants have not provided adequate written description for the genus comprising any *Lawsonia* spp., or any homolog or variant of any *Lawsonia* spp. or *Lawsonia intracellularis* OmpH protein. In response thereto, the presently pending claims have been amended to be directed towards SEQ ID No: 1. As a result of the amendments to these claims, reconsideration of the rejection is respectfully requested.

Claims 3, 8, 10, 17-21, and 39 have been rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. According to the Examiner, the specification is enabled for immunogenic polypeptides or compositions comprising a peptide of a *Lawsonia intracellularis* OmpH protein; however, the specification does not provide enablement for any derivatives of SEQ ID No: 1 capable of inducing a protective immune response or for vaccines comprising such polypeptides. In response thereto, the presently pending claims have been amended to be directed towards SEQ ID No: 1. As a result of the amendments to the claims, reconsideration of the rejection is respectfully requested.

Claims 13, 14, and 19 have been rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. More specifically, the Examiner holds that the claims contain subject matter that was not described in the specification in a manner as to enable one skilled in the art to make and/or use the presently claimed invention. More specifically, the Examiner holds that one skilled in the art cannot be assured of the ability to practice the invention as claimed in the absence of the availability of the

pALK13 plasmid. The Examiner holds that evidence of public availability of the expression plasmid of the claimed invention is required.

In response thereto, Applicants assure that the deposit has been made under the provisions of the Budapest Treaty and enclosed herewith is a copy of the deposit receipt for the claimed plasmid. Additionally, enclosed herewith is an Affidavit stating that the deposit has been accepted by the International Deposit Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on the present application. As a result, reconsideration of the rejection is respectfully requested.

Claims 21 and 39 have been rejected under 35 U.S.C. §112, first paragraph for lack of enablement. Additionally, claims 21 and 39 have been rejected under 35 U.S.C. §112, first paragraph, for lack of written description. Since these claims have been canceled from the present application in order to expedite the allowance of the present application, the rejections have been rendered moot.

In summary, as a result of the present amendment, the present application is now in condition for allowance, which allowance is respectfully requested. If any remaining issues exist, Applicants respectfully request to be contacted by telephone at (248) 539-5050.



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The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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Date: February 23, 2005

CERTIFICATE OF MAILING

Express Mail Mailing Label No: EV 571 723 629 US

Date of Deposit: February 23, 2005

I hereby certify that this correspondence is being deposited with the United States Postal Service as "Express Mail Post Office To Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Marie M. Lally